UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,790	06/20/2003	Richard Joseph Fagan	674575-2003	8260

20999 7590 04/26/2006

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
HISSONG, BRUCE D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,790	FAGAN ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a polypeptide which comprises or consists of the amino acid sequence of SEQ ID NO: 2, and claims 21, 32-34, insofar as they read on said polypeptide, classified in class 530, subclass 351.

II. Claims 11-15, drawn to purified nucleic acid molecules, vectors, and host cells, and claims 21, 32-34, insofar as they read on said purified nucleic acid molecules, vectors, and host cells, classified in class 435, subclass 69.1.

III. Claims 16-17, drawn to a ligand that binds specifically to a polypeptide of group I, and claims 21, 32, and 34, insofar as they read on said ligand, classified in class 530, subclass 387.1.

IV. Claims 18-20, drawn to a compound that increases or decreases the expression level or activity of a polypeptide of group I, and claims 21, 32, and 34, insofar as they read on said compound, classification could not be determined because no structure was provided.

V. Claims 22-24, 30, and 43, drawn to a method of diagnosing a disease in a patient comprised of assessing the level of the polypeptide of group I, and a kit for said method of diagnosing a disease, classified in class 436, subclass 503.

VI. Claims 22-23, 25-30, 40-42, and 49, drawn to a method of diagnosing a disease in a patient comprised of assessing the level of the nucleic acid encoding the polypeptide of group I, and a kit for said method of diagnosing a disease, classified in class 435, subclass 6.

VII. Claim 31, drawn to a method of using a polypeptide of group I, classified in class 514, subclass 2.

VIII. Claim 35-37, and 46, drawn to a method of treating a disease in a patient, classified in class 424, subclass 85.5.

IX. Claims 38, 47, drawn to a method of monitoring the therapeutic treatment of a disease, classified in class 435, subclass 4.

X. Claims 39 and 48, drawn to a method for the identification of a compound effective in the treatment and/or diagnosis of disease, classification could not be determined because no structure was provided.

XI. Claims 44-45, and 50, drawn to a transgenic or knockout non-human animal, classified in class 800, subclass 8.

B. The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-IV and XI are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptide of group I and the polynucleotide of group II are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of groups I and II have a separate status in the art as shown by their different classifications. In cases such as

this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. As such, it would be burdensome to search the inventions of groups I and II.

The polypeptide of group I and the antibody of group III are patentably distinct for the following reasons: while the inventions of both groups I and III are polypeptides, in this instance, the polypeptide of group I is a single chain molecule that functions as an interferon-gamma like secreted protein, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptide of group I and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptide of group I is a large molecule that contains potentially hundreds of regions to which an antibody must bind, whereas the antibody of group III is defined in terms of its binding specificity to a small structure within the disclosed SEQ ID NO: 2. Thus, immunization with the polypeptide of group I would result in the production of antibodies outside the scope of group III. Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group I and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies that bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. In addition, the technical literature search for the polypeptide of group I and the antibody of group III is not coextensive, e.g. antibodies may

be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

The polynucleotide of group II and the antibody of group III are patentably distinct for the following reasons: the antibody of group III includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibody of group III are composed of amino acids; polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II will not encode an antibody of group III, and an antibody of group III cannot be encoded by a polynucleotide of group II. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of groups II and III would impose a serious search burden since a search of the polynucleotide of group II would not be used to determine the patentability of an antibody of group III and vice-versa.

The compound of group IV is distinct from the molecules of groups I-III because, as a molecule that can increase or decrease the expression or activity of a polypeptide of group I, it has a function and utility that is distinct from those of groups I-III.

The transgenic/knockout animals, by virtue of being living entities, are distinct in structure, function, and utility, from the molecules of groups I-IV.

2. Inventions V-X are independent and distinct inventions, each from the other, because the methods are practiced with materially different process steps for materially different purposes, and each method requires a non-coextensive search because of different starting materials, process steps, and goals. The methods of groups V and VI are practiced with materially different materials and process steps, and both groups VI and VI have different process steps and goals from the methods of groups VII-X. The method of group VIII, drawn to a method of treatment, has separate materials, process steps, and goals than the methods of groups IX and X, drawn to methods of monitoring treatment, and methods of identification of a compound, respectively. The invention of group X, has separate process steps and goals that

are distinct from any of the inventions of groups V-IX. Finally, although group VII putatively represents a method of use, no information about any actual method has been provided, and therefore it is presumed to be distinct from the other inventions.

3. Invention XI is unrelated to inventions V-X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together.

4. Invention I is related to inventions V, VII-X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the polypeptide of group I can be used in a materially different process of using the product. For example, the polypeptide of group I can be used to raise antibodies.

5. Invention I is unrelated to invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not capable of use together.

6. Invention II is unrelated to inventions V and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together.

7. Invention II is related to inventions VI and VIII-X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the nucleic acids of group II can be used

in another, materially different process. For example, the nucleic acids of group II can be digested by restriction enzymes and used as molecular weight standards.

8. Invention III and IV are unrelated to inventions V-VII and IX-X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together.

9. Inventions III and IV are related to invention VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the method of invention VIII can be practiced with another materially different product, such as a polypeptide of group I.

C. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

D. Additionally, groups VIII-X are subject to further restriction. It is noted that the claims are drawn to examination of methods utilizing (*i*) polypeptides of group I, (*ii*) nucleic acids encoding said polyeptides, (*iii*) ligands for the polypeptides of group I or, (*iv*) a compound that increases or decreases the expression or activity of the polypeptides of group I. In order to be fully responsive, if Applicant elects group VIII, IX, or X, Applicant is then required to further elect a specific polypeptide, nucleic acid, ligand, or compound from (*i – iv* listed above). This is NOT an election of species. The claimed molecules (polypeptides, nucleic acids, ligands, compounds) are structurally distinct chemical compounds, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such molecule is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR

1.141. By statute "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant.....to elect that invention to which his claim shall be restricted." 37 CRF 1.142(a). See also 37 CFR 1.141(a). It is noted that search more than one of the claimed patentably distinct molecules represents a serious burden for the office.

E. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Applicant is also advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

F. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER